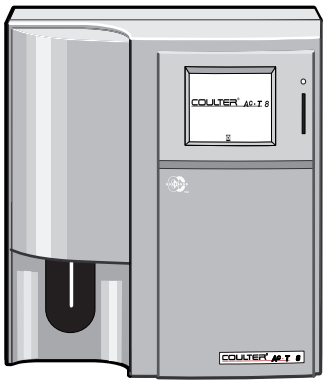
COULTER® A^{C}•T Series Analyzer

Reference



PN 4237288C (June 2003)

Beckman Coulter, Inc.
Fullerton, CA 92835

WARNINGS AND PRECAUTIONS

READ ALL PRODUCT MANUALS AND CONSULT WITH BECKMAN COULTER-TRAINED PERSONNEL BEFORE ATTEMPTING TO OPERATE INSTRUMENT. DO NOT ATTEMPT TO PERFORM ANY PROCEDURE BEFORE CAREFULLY READING ALL INSTRUCTIONS. ALWAYS FOLLOW PRODUCT LABELING AND MANUFACTURER'S RECOMMENDATIONS. IF IN DOUBT AS TO HOW TO PROCEED IN ANY SITUATION, CONTACT YOUR BECKMAN COULTER REPRESENTATIVE.

HAZARDS AND OPERATIONAL PRECAUTIONS AND LIMITATIONS

WARNINGS, CAUTIONS, and IMPORTANTS alert you as follows:

WARNING - Can cause injury.
CAUTION - Can cause damage to the instrument.
IMPORTANT - Can cause misleading results.

BECKMAN COULTER, INC. URGES ITS CUSTOMERS TO COMPLY WITH ALL NATIONAL HEALTH AND SAFETY STANDARDS SUCH AS THE USE OF BARRIER PROTECTION. THIS MAY INCLUDE, BUT IT IS NOT LIMITED TO, PROTECTIVE EYEWEAR, GLOVES, AND SUITABLE LABORATORY ATTIRE WHEN OPERATING OR MAINTAINING THIS OR ANY OTHER AUTOMATED LABORATORY ANALYZER.

WARNING Risk of operator injury if:

- All doors, covers and panels are not closed and secured in place prior to and during instrument operation.
- The integrity of safety interlocks and sensors is compromised.
- Instrument alarms and error messages are not acknowledged and acted upon.
- You contact moving parts.
- You mishandle broken parts.
- Doors, covers and panels are not opened, closed, removed and/or replaced with care.
- Improper tools are used for troubleshooting.

To avoid injury:

- Keep doors, covers and panels closed and secured in place while the instrument is in use.
- Take full advantage of the safety features of the instrument. Do not defeat safety interlocks and sensors.
- Acknowledge and act upon instrument alarms and error messages.
- Keep away from moving parts.
- Report any broken parts to your Beckman Coulter Representative.
- Open/remove and close/replace doors, covers and panels with care.
- Use the proper tools when troubleshooting.

CAUTION System integrity might be compromised and operational failures might occur if:

- This equipment is used in a manner other than specified. Operate the instrument as instructed in the Product Manuals.
- You introduce software that is not authorized by Beckman Coulter into your computer. Only operate your system's computer with software authorized by Beckman Coulter.
- You install software that is not an original copyrighted version. Only use software that is an original copyrighted version to prevent virus contamination.

IMPORTANT If you purchased this product from anyone other than Beckman Coulter or an authorized Beckman Coulter distributor, and, if it is not presently under a Beckman Coulter service maintenance agreement, Beckman Coulter cannot guarantee that the product is fitted with the most current mandatory engineering revisions or that you will receive the most current information bulletins concerning the product. If you purchased this product from a third party and would like further information concerning this topic, call your Beckman Coulter Representative.

REVISION STATUS

Initial Issue 9/96
Software Version 1.00.

Issue B, 3/97.
Software Version 1.04. Due to additions and deletions of material, pagination changed for some of this manual. Actual text changes, noted by change bars, occurred on pages: 1-1, 1-2, 1-6, 3-5, 3-7, 3-11, 4-1 through 4-20.

Issue C, 6/03
Changes were made to change the company name from Coulter Corporation to Beckman Coulter Inc.

Note: Changes that are part of the most recent revision are indicated by a black bar in the margin of the amended page.

This document applies to the latest software listed and higher versions. When a subsequent software version changes the information in this document, a new issue will be released.

REVISION STATUS

CONTENTS

WARNINGS AND PRECAUTIONS, ii

REVISION STATUS, iii

INTRODUCTION, ix

HOW TO USE YOUR COULTER AC•T SERIES ANALYZER MANUALS, ix

ABOUT THIS MANUAL, ix

CONVENTIONS, x

SYMBOLS, x

TOUCH SCREEN ICONS, xi
Main Screen Icons, xi
Setup Screen Icons, xii
Diluter Functions Screen Icons, xiii
Diagnostic Functions Screen Icons, xiv
Sample Results Screen Icons, xv
Sample ID Screen Icons, xv

1 USE AND FUNCTION, 1-1

1.1 INTENDED USE, 1-1
General, 1-1
Parameters, 1-1

1.2 METHOD HISTORY, 1-2
Development, 1-2
Hemoglobinometry, 1-3
Leukocyte Volume, 1-3

1.3 CONTROLS AND CALIBRATORS, 1-3
Calibrator, 1-3
Cell Controls, 1-3

1.4 REAGENTS, 1-3
COULTER AC•T Pak or COULTER AC•T Tainer, 1-4
Diluent, 1-4
Lytic Reagent, 1-4
Shutdown Diluent, 1-4

1.5 COMPUTER SOFTWARE, 1-4

1.6 MATERIAL SAFETY DATA SHEETS (MSDS), 1-4

2 INSTALLATION, 2-1

2.1 DELIVERY INSPECTION, 2-1

2.2 SPECIAL REQUIREMENTS, 2-1
Space and Accessibility, 2-1

Electrical Input, 2-1
Ambient Temperature and Humidity, 2-1
Printer, 2-1

2.3 REAGENT CONNECTIONS, 2-1

3 OPERATION PRINCIPLES, 3-1

3.1 GENERAL PRINCIPLES, 3-1
Coulter Method, 3-1
Effect of Reagent on the Cells, 3-1

3.2 NORMAL SAMPLE FLOW (Whole-Blood Mode), 3-1

3.3 COUNTING AND SIZING, 3-2
Red and White Cell Counting, 3-2
Coincidence Correction, 3-3
Voting, 3-3
WBC Count and Size Distribution, 3-3
RBC Count and Size Distribution, 3-3
Plt Count and Size Distribution, 3-3
Sweep Flow, 3-3
Computed Parameters, 3-4
Aperture Alert, 3-4

3.4 MEASUREMENT OF HEMOGLOBIN CONCENTRATION, 3-5

3.5 DERIVATION OF PARAMETERS, 3-5
White Blood Cell (WBC) Count, 3-5
Red Blood Cell (RBC) Count, 3-5
Platelet (Plt) Count, 3-5
Hemoglobin (Hgb) Concentration, 3-6
Mean Corpuscular Volume (MCV), 3-6
Hematocrit (Hct), 3-6
Mean Corpuscular Hemoglobin (MCH), 3-7
Mean Corpuscular Hemoglobin Concentration (MCHC), 3-7
Lymphocyte (LY#) Count, 3-7
Lymphocyte (LY%) Percent, 3-7

4 SPECIFICATIONS/CHARACTERISTICS, 4-1

4.1 INSTRUMENT SPECIFICATIONS, 4-1
Dimensions/Weight, 4-1
Power, 4-1
Input, 4-1
Consumption, 4-1
Installation Category, 4-1
Temperature, Ambient Operating, 4-1
Humidity, 4-1
Recommended Reagents, 4-1
Recommended Control, 4-2
Recommended Calibrator, 4-2

Recommended Anticoagulant, 4-2
Sample Volume Aspirated, 4-2
Aperture Size, 4-2
Storage, 4-2
Throughput, 4-2
Sample Identification, 4-2
Output, 4-2

4.2 PERFORMANCE SPECIFICATIONS, 4-2
Imprecision, 4-2
Operating Range, 4-3
Accuracy, 4-4
Linearity, 4-6
Background Counts, 4-6
Carryover, 4-7
Mode to Mode, 4-7

4.3 PERFORMANCE CHARACTERISTICS, 4-7
Imprecision, 4-7
Accuracy, 4-8
Reference Ranges, 4-11
Carryover, 4-12
Mode to Mode, 4-13

4.4 INTERFERING SUBSTANCES, 4-14
WBC, 4-14
RBC, 4-14
Hgb, 4-14
MCV, 4-14
Plt, 4-14
Hct, 4-14
MCH, 4-14
MCHC, 4-15
LY, 4-15

5 PRECAUTIONS/HAZARDS, 5-1

5.1 CAUTIONS, 5-1
Definition, 5-1
List of CAUTIONS, 5-1

5.2 IMPORTANTS, 5-1
Definition, 5-1
List of IMPORTANTS, 5-1

5.3 WARNINGS, 5-2
Definition, 5-2
Biological Hazards, 5-2
Moving Parts, 5-3

F LOG SHEETS, A-1

REFERENCES, REFERENCES-1

GLOSSARY, GLOSSARY-1

INDEX, INDEX-1

BECKMAN COULTER, INC. CUSTOMER END USER LICENSE AGREEMENT

TRADEMARKS

ILLUSTRATIONS

1.1 COULTER AC•T 8 Series Analyzer, 1-1
3.1 Coulter Method of Counting and Sizing, 3-1
3.2 Sweep Flow, 3-4

TABLES

4.1 **Imprecision Specifications**, 4-3
4.2 **Operating Range**, 4-4
4.3 **CBC Accuracy at 20-25°C**, 4-4
4.4 CBC Accuracy at 16-35°C, 4-6
4.5 **Linearity Limits**, 4-6
4.6 **Background Counts**, 4-6
4.7 Imprecision, Whole Blood in K3EDTA, 4-7
4.8 Imprecision, 4C PLUS Normal Cell Control , 4-7
4.9 Imprecision, 4C PLUS Abnormal Low Cell Control, 4-8
4.10 Imprecision, 4C PLUS Abnormal High Cell Control , 4-8
4.11 ACCURACY, COMPARED SAMPLES 20-25° C WHOLE BLOOD MODE, 4-8
4.12 Accuracy, Compared Samples16 - 20° C Whole Blood Mode, 4-10
4.13 Accuracy, Compared Samples 25-35° C Whole Blood Mode, 4-11
4.14 Normal Population Study, 4-12
4.15 Imprecision Analysis By Carryover Whole Blood Mode, 4-13
4.16 Whole Blood Mode vs. Predilute Mode, 4-14
6.1 **ACTION LOG**, A-3
6.2 **MAINTENANCE LOG**, A-5
6.3 **REAGENT LOG**, A-7
7.1 Ac*T Series Consumables, B-1

This introductory section contains the following topics:

- How to use your COULTER® A^{C}•T Series Analyzer Manuals
- About this Manual
- Conventions
- Symbols
- Touch Screen Icons

HOW TO USE YOUR COULTER A^{C}•T SERIES ANALYZER MANUALS

Use the **Reference** manual for in-depth information about:

- What the instrument does
- What special requirements the instrument has (for example, space, accessibility, power)
- What methods it uses
- What the instrument specifications are
- How to safely use the instrument.

Use the **Operator's Guide** for:

- Running your instrument day to day
- Reviewing unusual results

Use the **Special Procedures and Troubleshooting** manual for:

- Cleaning, replacing, or adjusting a component of the instrument.
- Reviewing unusual results (how to read a result report and what flags mean).
- Troubleshooting problems with your instrument.

Use the **Host Computer Specification** to:

- Find the information needed to program the transmission interface between your A^{C}•T Series analyzer, and your laboratory's host computer.

See the Documentation page on the back cover of this manual for the contents of each manual. It can help you to determine quickly which manual contains the information you need.

ABOUT THIS MANUAL

Your COULTER A^{C}•T Series Anayzer **Reference** manual is a reference source of information on what the system does.

This information is organized as follows:

- Chapter 1, Use and Function
  Contains the intended use of the instrument, a brief history of the methods used by the instrument, the reagents, calibrator and controls used, and a short description of the major components and options.

- Chapter 2, Installation
  Contains the instrument requirements for space, accessibility and power.
- Chapter 3, Operation Principles
  Contains the descriptions of the Coulter Method for cell counting, the normal sample flow through the instrument, how counting and sizing are accomplished, how the parameters are derived and a description of the Aperture Alert.
- Chapter 4, Specifications
  Details the instrument, performance specifications and the interfering substances.
- Chapter 5, Precautions/Hazards
  Contains all the WARNING, CAUTION and IMPORTANT messages that appear throughout the A^{C}•T Series analyzer manuals.
- Appendices
  The appendices provide reference material on the following topics:
  - Log Sheets

This manual also includes a Glossary, recommended References and an Index.

CONVENTIONS

This manual uses the following conventions:

Bold font indicates A^{C}•T Series analyzer manual titles.

Bold indicates a screen icon.

SYMBOLS

These symbols alert you to possible injury, damage to instrument, or how to avoid obtaining misleading results.

Wear standard laboratory attire.

Keep hands away from probe area. Probe moves up and down.

Unplug the A^{C}•T analyzer before continuing.

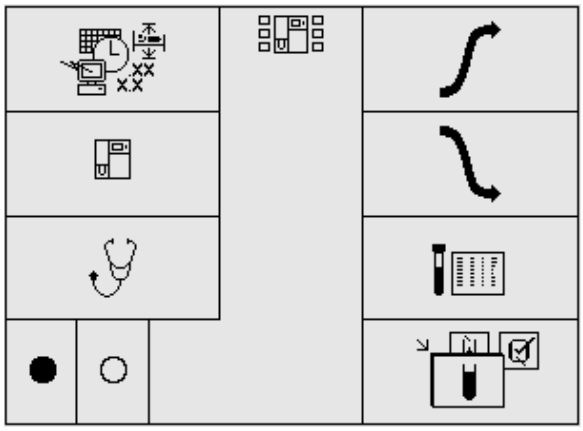
Go to.

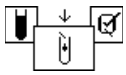
For further information, see the **Special Procedures and Troubleshooting** manual.

‡ This symbol indicates that, at the time of instrument release, this product was not available.

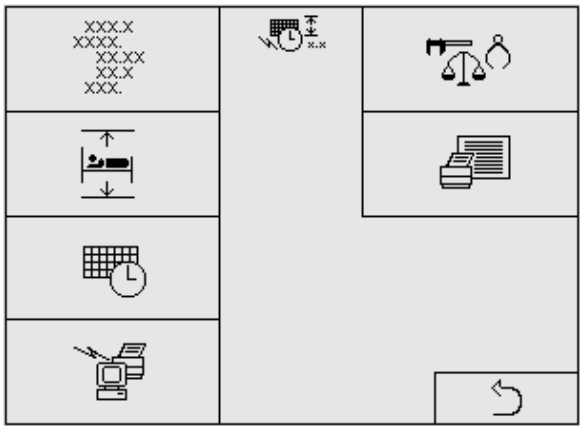
TOUCH SCREEN ICONS

Main Screen Icons



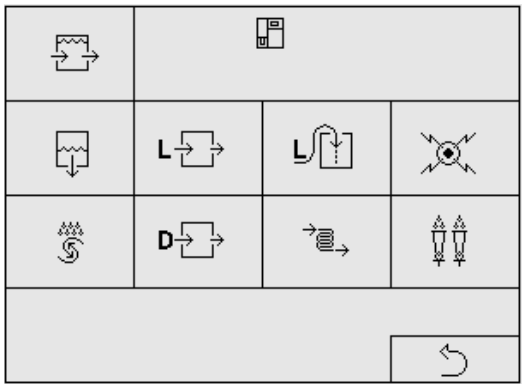
Setup	Shutdown
Diluter Functions	Sample Results Screen
Diagnostics	 Analyzing Mode
Darken Screen	Whole Blood Mode
Lighten Screen	Predilute Mode
Startup	A^{C}•T Tron‡ Mode

Setup Screen Icons



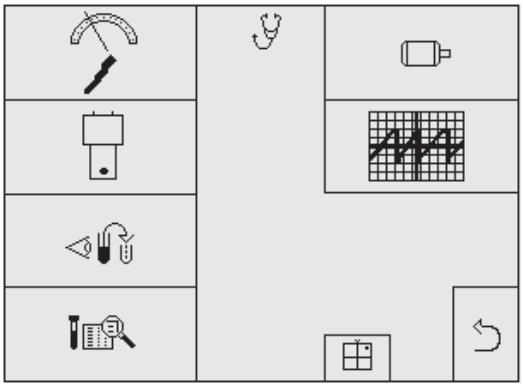
Units	Calibration Factors
Patient Limits	Print Setup Report
Date/Time	Exit
Transmission	

Diluter Functions Screen Icons



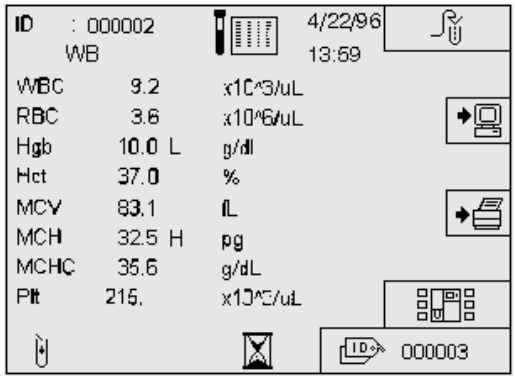
Wet Prime	Dispense Lytic Reagent
Drain Baths	Prime Sweepflow
Rinse + Mix	Zap Apertures
Dry Prime Lytic Reagent	Clean Baths
Dry Prime Diluent	Exit

Diagnostic Functions Screen Icons



Voltages/Sensors	Motors
Solenoids	Pulse Test
Verify Predilute	Prepare to Ship
Sample Details	Exit

Sample Results Screen Icons



Dispense Diluent	Enter Patient ID
Resend to Host	Go to Main Menu
Print Sample Results	In Progress

Sample ID Screen Icons

1	2	3	000002
4	5	6	
7	8	9	0

Delete	Exit
Save and Exit	

1.1 INTENDED USE

General

The COULTER A^{C}•T Series analyzers (Figure 1-1), are quantitative, automated hematology analyzers. The A^{C}•T 10 Series is also a leukocyte differential counter. Both instruments are For In Vitro Diagnostic Use in clinical laboratories.

Figure 1.1 COULTER A^{C}•T 8 Series Analyzer

Parameters

These systems determine the following hematologic parameters of whole-blood specimens.

A^{C}•T 8 Automated Cell Counter		A^{C}•T 10 Automated Cell Counter	
WBC	MCV	WBC	Hct
RBC	MCH	LY#	MCV
Hgb	MCHC	LY%	MCH
Hct	Plt	RBC	MCHC
		Hgb	Plt

These parameters are defined as:

WBC White Blood Cell or leukocyte count

- LY # Lymphocyte number
- LY % Lymphocyte percent

RBC Red Blood Cell or erythrocyte count

Hgb Hemoglobin concentration

Hct Hematocrit (relative volume of erythrocytes)

MCV Mean Corpuscular (erythrocyte) Volume

MCH Mean Corpuscular (erythrocyte) Hemoglobin

MCHC Mean Corpuscular (erythrocyte) Hemoglobin Concentration

Plt Platelet or thrombocyte count

Unless otherwise stated, all parameter results are shown in US unit format.

The purpose of the A^C•T Series analyzer is to identify the normal patient, with all normal system-generated parameters, and to flag or identify patient results that require additional studies.

1.2 METHOD HISTORY

Development

W.H. Coulter describes the Coulter principle:[1]

> A suspension of blood cells is passed thru a small orifice simultaneously with an electric current. The individual blood cells passing through the orifice introduce an impedance change in the orifice determined by the size of the cell. The system counts the individual cells and provides cell size distribution. The number of cells counted per sample is approximately 100 times greater than the usual microscope count to reduce the statistical error by a factor of approximately 10 times.

This substantial improvement in precision over previous methods helped to establish the erythrocyte count as a sensitive index of erythropoietic dyscrasia, particularly when considered together with Hct and Hgb measurements.[2]

The COULTER COUNTER® Model S analyzer was the first instrument that automated simultaneous multiparameter measurements on blood. Brittin et al., Gottmann, and Hamilton and Davidson, reviewed the performance and clinical value of the Model S.[3,4,5]

Refinements of the COULTER COUNTER analyzer to provide accurate size (volume) distribution data led to a reawakening of interest in pathological erythrocyte size distribution, first aroused by Price-Jones.[6,7]

Among the advantages offered by the Coulter method of counting and sizing was the ability to derive an accurate Hct measurement by summing the electronic volume of erythrocytes. England et al. speculated that electronic Hct measurements did not have the trapped plasma error of centrifugal Hct measurements.[8]

Bull et al. described the use of a COULTER COUNTER analyzer for counting thrombocytes.[9] This method, useful as it was, depended on preparing thrombocyte-rich plasma to avoid counting erythrocytes as thrombocytes. Mundschenk et al. and Schulz and Thom discussed the possibility of counting thrombocytes in the presence of erythrocytes and classifying them by size.[10,11] Electronic refinements in the Model S-PLUS enhanced the accuracy of the hydrodynamic method. Von Behrens and Paulus have also cited the feasibility of counting thrombocytes by the Coulter method.[12,13]

Hemoglobinometry

The lytic reagent prepares the blood so that leukocytes can be counted and the amount of hemoglobin sensed. The lytic reagent rapidly and simultaneously destroys the erythrocytes and converts a substantial proportion of the hemoglobin to a stable cyanide-containing pigment, while it leaves the leukocyte nuclei intact. The absorbance of the pigment is directly proportional to the hemoglobin concentration of the sample.

The accuracy of this method equals that of the hemoglobin cyanide method, the reference method of choice for hemoglobinometry recommended by the International Committee for Standardization in Haematology.[14]

Leukocyte Volume

Electronic leukocyte volume analysis, which is the basis of differential percentage, has been used since 1967.[15] It has been evaluated as a possible adjunct to the manual differential white cell count.[16,17,18,19]

Under the controlled condition of lysis, a chemical reaction demonstrates one distinct population of leukocytes: lymphocytes.[20]

Mature normal lymphocytes and variant atypical lymphocytes, being the smallest of the WBC cells, tend to occupy the size range from 35 to 90 fL.

1.3 CONTROLS AND CALIBRATORS

To help you determine laboratory procedures, you can purchase the Physicians Office Laboratory Guideline, POL2-T, from the National Committee for Clinical Laboratory Standards (NCCLS), 771 E. Lancaster Avenue, Villanova, PA 19085. Phone (215) 525-2435.

Calibrator

The COULTER S-CAL® calibrator kit is a recommended alternative to the whole-blood reference method of calibration. S-CAL calibrator is traceable to reference methods and materials. Use S-CAL calibrator to ensure accurate instrument measurements.

Cell Controls

Either COULTER A^{C}•T Tron‡ cell control or COULTER 4C® PLUS cell control is available to supply a stable reference control for use with this system. Cell controls monitor the performance of the diluting, counting, sizing, and Hgb measurements.

Beckman Coulter suggests that you run controls daily. Federal, state or local regulatory or certification agencies may require more frequent quality control. Check with the appropriate agency for further information.

1.4 REAGENTS

Beckman Coulter recommends these reagents. All stated performance characteristics in this manual are based on the use of the A^{C}•T Series analyzer with these reagents. Refer to the container's label for detailed information before using the reagent.

COULTER A^{C}•T Pak or COULTER A^{C}•T Tainer

For use with the A^{C}•T Series analyzer, Coulter manufactures the COULTER A^{C}•T Pak or COULTER A^{C}•T Tainer. Either contains Reagent 1 diluent and Reagent 2 lytic reagent. The COULTER A^{C}•T Tainer also contains COULTER A^{C}•T Rinse Shutdown Diluent, Reagent 3.

Diluent

Reagent 1 is an isotonic electrolyte solution that:

- Dilutes the whole-blood samples.
- Stabilizes cell membranes for accurate counting and sizing.
- Conducts aperture current.
- Rinses instrument components between analyses.
- Prevents duplicate cell counts by using the sweep-flow process.

Lytic Reagent

Reagent 2 is a lytic reagent that

- Lyses red blood cells (RBCs) for WBC count and hemoglobin measurement.
- Causes a differential shrinkage of leukocytes into predictable volume components.

Shutdown Diluent

COULTER A^{C}•T Rinse Shutdown Diluent prevents protein buildup that occurs in and around the apertures.

1.5 COMPUTER SOFTWARE

This system is run by computer software. Be sure to use only the Software Card supplied by Beckman Coulter. Observe the copyright statement on the card.

1.6 MATERIAL SAFETY DATA SHEETS (MSDS)

To obtain an MSDS for COULTER reagents used on the A^{C}•T Series analyzer:

1. In the USA, write to
   Beckman Coulter, Inc.
   Attn: MSDS Requests
   P.O. Box 169015
   Miami, FL 33116-9015
2. Outside the USA, call your Beckman Coulter Representative.

2.1 DELIVERY INSPECTION

Your instrument is tested before it is shipped from the factory. International symbols and special handling instructions tell the carrier how to treat this electronic instrument.

When you receive your instrument, carefully inspect the carton. If you see signs of mishandling or damage, file a claim with the carrier immediately. If the instrument is insured separately, file a claim with the insurance company.

2.2 SPECIAL REQUIREMENTS

Specific step-by-step instructions for installing the A^{C}•T Series analyzer are in the **Getting Started** manual, Chapter 1. Before you install your unit, determine where you want to place it. Consider the following requirements.

Space and Accessibility

In addition to the space required for the unit itself, arrange for

- Comfortable working height.
- At least 26 cm (10 in.) on each side is the preferred access to perform service procedures.
- At least 7.5 cm (3 in.) behind for cabling and ventilation.

Electrical Input

The power cord must plug directly into the outlet. Do not use an extension cord.

This instrument requires:

- An independent protected circuit: for the printer and for the instrument itself.
- The building outlet to be properly grounded and the electrical panel to be protected against power fluctuations.
- A female receptacle outlet furnishing single-phase input power.
- A ground path capable of carrying the full current of the circuit (confirmed third-wire earth ground).

Ambient Temperature and Humidity

Keep room temperature between 16°C and 35°C (61°F and 95°F) and humidity no higher than 85 percent without condensation.

Printer

Use the printer and printout paper that come with your system. See the printer's operating manual for instructions on how to use it. Place the printer in any location convenient to the instrument.

2.3 REAGENT CONNECTIONS

Reagent packs, and the waste collection container tubing, are attached to the connectors. You can place reagents below the instrument so long as they are no more than 91.44 cm (36 in.) below and you do not use more than the 182.88 cm (6 ft) of tubing provided. Do not place reagents above the instrument. The reagent connections are illustrated in the **Getting Started** manual, Chapter 1.

3.1 GENERAL PRINCIPLES

Coulter Method

The Coulter method accurately counts and sizes cells by detecting and measuring changes in electrical resistance when a particle (such as a cell) in a conductive liquid passes through a small aperture. Figure 3-1 illustrates this principle.

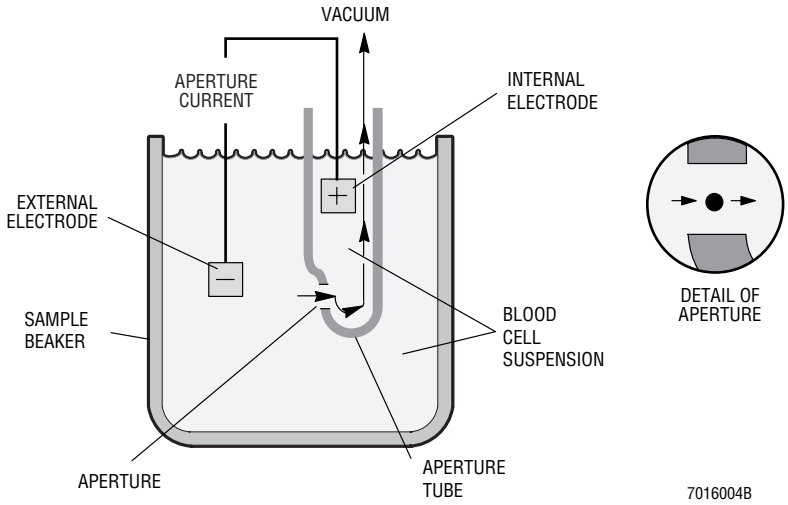


Figure 3.1 Coulter Method of Counting and Sizing

As each cell goes through the aperture, it impedes the current and causes a measurable pulse. The number of pulses signals the number of particles. The height of each pulse is proportional to the volume of that particle.

While the number of pulses indicates particle count, the amplitude of the electrical pulse produced depends on the cell's volume. Theoretical analysis of the behavior of particles within an aperture shows that the height of the electrical pulse produced by the cell is the characteristic that most nearly shows proportionality to the cell volume.[21,22,23,24]

Effect of Reagent on the Cells

In a counting system highly sensitive to the volume of the individual particles being counted, the conductive liquid, in which the particles are suspended, must have a minimum influence on their biological integrity and, thus, their size.

The reagents used for leukocyte counting must destroy erythrocytes without significantly affecting the ability to count leukocytes.They must work quickly enough to satisfy the processing time of the instrument.

3.2 NORMAL SAMPLE FLOW (Whole-Blood Mode)

1. The aspiration syringe draws 12 µL of whole blood into the probe. The instrument reads Hgb blank 2. The WBC and RBC baths drain. The WBC bath rinses and drains. The diluent syringe dispenses diluent into the WBC bath to pre-fill it. The instrument reads Hgb Blank 1.

2. The probe moves to the WBC bath and the diluent and sample syringes dispense the sample (12 µL) and diluent into the WBC bath, making a 215:1 Dilution. The RBC Bath rinses and mixing bubbles enter the WBC bath to mix the solution.
3. The aspiration syringe aspirates 100 µL of the 215:1 dilution into the probe for the RBC/Plt dilution. The Vacuum Isolator Chamber (VIC) drains. The RBC bath rinses and drains. The diluent syringe dispenses diluent into the RBC bath to prefill it.
4. The lytic reagent syringe sends lytic reagent to the WBC bath for a final 250:1 dilution, while the diluent and aspiration syringes dispense 100 µL of the 215:1 dilution and additional diluent into the RBC bath for a final RBC/Plt dilution of 6250:1.
5. Mixing bubbles enter the baths to mix (WBC for 2.4 seconds, RBC for 1.7 seconds) the bath contents.
6. Both dilutions (WBC and RBC/Plt) are drawn through the apertures via regulated vacuum.
7. The instrument counts for 12 seconds (three consecutive periods of 4 seconds each) to count the WBCs, RBCs and Plts. After counting finishes, the flow ends.
8. The RBC bath drains and rinses; the VIC drains. The instrument takes an Hgb sample reading.
9. The WBC drains and the instrument analyzes the data.
10. The WBC rinses. The VIC drains. The instrument analyzes the WBC count.
11. The WBC drains. The instrument displays results on the screen and prints the results (if a printer is available) and sends data to the host computer if available.
12. The WBC rinses. The probe moves to the aspirate position.
13. The VIC drains, the instrument zaps the apertures. The cycle counter increments as the diluent reservoir fills. The instrument is ready for the next sample.

3.3 COUNTING AND SIZING

The A^{C}•T Series system uses triplicate counting, internal voting criteria and proprietary flagging algorithms to confirm parameter results prior to reporting. After the computer corrects for coincidence, it compares the three counts each for WBC, RBC, Plt. If the unit finds disagreement among all count periods or does not meet other internal criteria, the instrument displays a total voteout.

IMPORTANT In rare instances, a transient or partial aperture blockage may not be detected by any of these methods. Therefore, verify flagged results for accuracy and review any result that exceeds your patient reference ranges.

Red and White Cell Counting

Each bath has an aperture: one for counting RBC/Plt and one for counting WBC. The counts take place concurrently. The system draws the WBC dilution through the WBC aperture while it draws the RBC/Plt dilution through the RBC/Plt aperture. The system counts for three consecutive periods of 4 seconds each.

During the RBC count, pulses that represent cells of 36 fL or greater are classified as red cells. During the WBC count, pulses that represent cells of 35 fL or greater are classified as white cells.

Both counts then go to the computer for coincidence correction and voting.

The count cycle is monitored for abnormal variations using the Aperture Alert (see Aperture Alert Heading).

Coincidence Correction

Depending upon concentration, more than one cell can go through the aperture at the same time. When cells coincide, however, the analyzer counts only one pulse. The frequency of coincidence is proportional to the concentration. The system corrects results for coincidence.

Voting

After the computer corrects for coincidence, it compares the three counts each for RBC, WBC, Plt, and LY#.

If there is disagreement among all three count periods for WBC, RBC, Plt, and LY#, there is a total voteout and dashes (- - - - -) appear on the display and the printout instead of results for the affected parameter.

Beckman Coulter uses triplicate counting and voting to maximize the accuracy of results. In rare instances, a transient blockage can cause an erroneous result. Always verify flagged or questionable results for accuracy.

WBC Count and Size Distribution

During the WBC sensing period, pulses that represent cells 35 fL and larger are classified as white cells. On the A^C•T 10, pulses that represent cells from 35 fL to approximately 100 fL are classified as lymphocytes.

RBC Count and Size Distribution

During RBC sensing, pulses that represent cells 36 fL and larger are classified as RBCs.

Plt Count and Size Distribution

During RBC sensing, pulses from 2 fL to 20 fL are classified as platelets. To ensure that the Plt count accurately reflects the cell population, whenever the Plt data accumulation is below a predetermined value, Plt sensing is extended for up to eight 3-second sensing periods. The extended time is taken into consideration in the Plt calculations. Platelet pulses are sorted by size into 64 channels to produce a platelet histogram. The computer then checks to see if the Plt distribution fits the curve criteria that represent platelets from 0 fL to 70 fL. If the curve criteria are not met, there is a no-fit condition, and an * flag (Review results) appears in the flag area.

Sweep Flow

The sweep flow is a steady stream of diluent that flows behind the RBC aperture during RBC/Plt sensing. This keeps cells from swirling back into the sensing zone and being counted as platelets; see Figure 3-2.

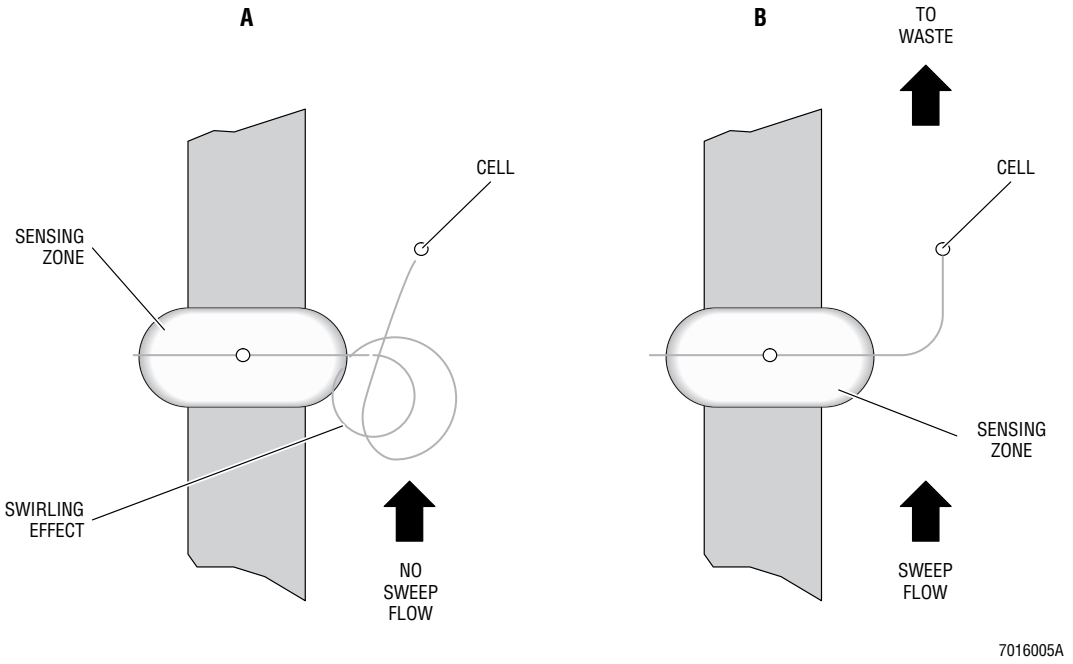


Figure 3.2 Sweep Flow

Computed Parameters

The computer computes Hct, MCH, MCHC and LY%.

Aperture Alert

The Aperture Alert is a software function that:

- checks for sample integrity during data analysis.
- monitors the integrity of results.

Whole-blood specimens have standard patterns that the software monitors during analysis. Differences from these standard patterns indicate a deviation in the sample during analysis. Such deviations can compromise the integrity of the result by interfering with the analysis. The A^{C}•T Series system monitors these deviations and flags them with an Aperture Alert. See the **Special Procedures and Troubleshooting** manual, Heading 3.2, What Flags Mean.

The system also monitors analysis according to internally stored criteria consisting of:

- several different statistics that are applied to the WBC and RBC sample data.
- verification of expected standard relationships among parameters such as RBC, Hgb, and Hct.

The Aperture Alert suppresses results for the affected parameters when the sample lacks accurate data to pass the internal criteria.

3.4 MEASUREMENT OF HEMOGLOBIN CONCENTRATION

The system uses the lysed WBC dilution to measure Hgb. The absorbance of light from an incandescent lamp is measured at 525 nm through the optical path length of the bath. A beam of light from the lamp passes through the sample, through a 525-nm filter, and is measured by a photodiode. The signal is amplified and the voltage is measured and compared to the blank reference reading.

3.5 DERIVATION OF PARAMETERS

Mathematic expressions in this section are in US units of measurement. You can change the units of measurement in the instrument software (see the **Getting Started** manual, Customizing Software).

White Blood Cell (WBC) Count

WBC is the number of leukocytes measured directly, multiplied by a calibration constant. Expressed in thousands of leukocytes per microliter of whole blood.

$$WBC = n \times 10^3 \text{ cells per } \mu L$$

Red Blood Cell (RBC) Count

RBC is the number of erythrocytes measured directly, multiplied by a calibration constant. Expressed in millions of erythrocytes per microliter of whole blood.

$$RBC = n \times 10^6 \text{ cells per } \mu L$$

Platelet (Plt) Count

Plt is the number of thrombocytes derived from directly measured platelet pulses, multiplied by a calibration constant. Expressed in thousands of thrombocytes permicroliter of whole blood.

$$Plt = n \times 10^3 \text{ cells per } \mu L$$

Hemoglobin (Hgb) Concentration

Hgb is determined from the absorbance computed from the ratio of the blank to the sample photocurrent readings. This number is multiplied by a constant and expressed in grams of hemoglobin per deciliter of whole blood.

$$\text{Hgb (g/dL)} = \text{Calibration Factor} \times \text{Calibration Constant} \times \text{Absorbance}$$

$$\text{Absorbance} = \text{Log}_{10}\left(\frac{\text{Blank Photocurrent}}{\text{Sample Photocurrent}}\right)$$

Mean Corpuscular Volume (MCV)

MCV is determined by measuring the average volume of individual erythrocytes. This number is multiplied by a coincidence correction factor and a calibration factor. The reported value expresses MCV in femtoliters.

Hematocrit (Hct)

This is the computed relative volume of erythrocytes, expressed in percent.

$$\text{Hct (\%)} = \frac{\text{RBC} \times \text{MCV}}{10}$$

Mean Corpuscular Hemoglobin (MCH)

This is the computed weight of hemoglobin in the average erythrocyte, expressed in picograms.

$$\text{MCH (pg/cell)} = \frac{\text{Hgb}}{\text{RBC}} \times 10$$

Mean Corpuscular Hemoglobin Concentration (MCHC)

This is the computed average weight of hemoglobin in a measured dilution, expressed in grams of hemoglobin per deciliter of erythrocytes.

$$\text{MCHC (g/dL)} = \frac{\text{Hgb}}{\text{Hct}} \times 100$$

Lymphocyte (LY#) Count

LY# is the number of lymphocytes measured directly and expressed in thousands of leukocytes per microliter of whole blood.

$$\text{LY\#} = n \times 10^3 \text{ cells per } \mu\text{L}$$

Lymphocyte (LY%) Percent

LY% is the relative number of leukocytes that are lymphocytes, expressed in percent.

$$\text{LY\%} = \frac{\text{LY\#}}{\text{WBC}} \times 100$$

4.1 INSTRUMENT SPECIFICATIONS

Dimensions/Weight

Width 38 cm (15 in.)
Height 42 cm (16.5 in.)
Depth 39 cm (15.4 in.)
Weight 15 kg (33 lb)

Power

Input

100 ±10%, 50/60 Hz
120 ±10%, 50/60 Hz
220 ±10%, 50/60 Hz
240 ±10%, 50/60 Hz

Note: For international applications, the electrical input line cord of the instrument may be replaced with an equivalent grounded and shielded line cord, to meet local wiring codes or ac plug standards. Use these specifications:

Voltage rating	250 VRMS
Current rating	6 A
Wire size	3-18 AWG, Diameter = 1.19 mm, 41 x 34, stranded ASTM B-3
Color code	International CEE standard 7
Shield	Braided tinned copper, 85% coverage minimum (connected to earth at coupler connector)
Approvals	UL listed, CSA approved, or applicable national standard

Consumption

Less than 250 W

Installation Category

Category II per IEC 1010-1

Temperature, Ambient Operating

16°C to 35°C (61°F to 95°F)

Humidity

30 to 85% without condensation

Recommended Reagents

COULTER A^{C}•T Pak or COULTER A^{C}•T Tainer, either of which contains diluent (Reagent 1) and lytic reagent (Reagent 2).

COULTER A^{C}•T Rinse Shutdown Diluent (Reagent 3) prevents protein buildup that occurs in and around the apertures.

Recommended Control

COULTER A^{C}•T Tron‡ cell control or COULTER 4C® PLUS cell control: abnormal low, normal and abnormal high.

Recommended Calibrator

COULTER S-CAL calibrator.

Recommended Anticoagulant

A salt of EDTA (K_2, K_3, or Na_2) with the proper proportion of blood to anticoagulant, as specified by the tube manufacturer.

Sample Volume Aspirated

12 µL whole blood in whole blood analyzing mode
735 µL prediluted blood in predilute analyzing mode

Aperture Size

WBC 100 µm x 75 µm

RBC 50 µm x 60 µm

Storage

A single sample is stored for recall or display until next cycle starts or system is turned off.

Throughput

A minimum of 50 samples per hour with results displayed in 60 seconds or less.

Sample Identification

Mandatory sample ID of up to 6 digits, entered automatically or by operator on the touch screen.

Output

The Sample Results screen shows sample identification number, sample mode, sample results and gives messages.

The system can transmit startup, sample, and control data to a host computer.

The system provides a printout of all data.

4.2 PERFORMANCE SPECIFICATIONS

The performance specifications stated apply only to an instrument that has been properly maintained as indicated in the **Special Procedures and Troubleshooting** manual, using a recommended reagent system.

Imprecision

Imprecision is based on 31 replicate determinations of the same sample. Imprecision limits for the Complete Blood Count (CBC) parameters are specified as a coefficient of variation (CV); the imprecision limits for LY% are specified as a Standard Deviation (SD).

Results are acceptable when the %CV or SD values, as appropriate, are within the limits in Table 4-1.

Table 4.1 Imprecision Specifications

Parameter	Level	Units	%CV	SD
WBC	6.0 - 15.0	x 10^3 cells/µL	≤3.0	
RBC	3.00 - 6.00	x 10^6 cells/µL	≤3.0	
Hgb	12.0 - 18.0	g/dL	≤2.0	
MCV	80.0 - 100.0	fL	≤3.0	
Plt	200 - 500	x 10^3 cells/µL	≤7.0	
LY%	20 - 40	%		≤1.5

Operating Range

The operating range listed in Table 4-2 is the range of results over which the A^C•T Series instruments display, print and transmit results. The A^C•T analyzer flags values between the linear range and the operating range.

Table 4.2 Operating Range

Parameter	Range	Units
WBC	0.0 - 150	x 10^3 cells/µL
RBC	0.00 - 8.00	x 10^6 cells/µL
Hgb	00.0 - 30.0	g/dL
MCV	50.0 - 130.0	fL
Plt	000 - 3000	x 10^3 cells/µL
LY%	0 - 100	%

Accuracy

Accuracy of the instrument is adjustable to within the resolution of the readout to agree with a predetermined reference value at any point in the operating range. Accuracy for WBC, RBC, Hgb and Plt is a correlation coefficient of greater than or equal to 0.95. The mean difference or mean percent differences for all parameters is within the limits in Tables 4-3 and 4-4.

Accuracy of lymphocyte percent is specified using mean difference (in units %) where each difference is equal to the A^C•T analyzer result minus the comparator result.

Accuracy determination must be performed on a valid data set (that is, acceptable performance of calibration, linearity and precision) as compared to a Beckman Coulter instrument with Coulter Histogram Differential (CHD).

Table 4.3 CBC Accuracy at 20-25°C

Parameter	Difference (whichever is greater)	95% Confidence
WBC # 0-2.0	±0.3 or ±5%	±0.3 x 10^3 cells/µL
2.1 - 4.0	±0.3 or ±5%	±0.4 x 10^3 cells/µL
≥ 4.1	±0.3 or ±5%	±14%
RBC	±0.05 or ±5%	±10.0%
Hgb	±0.2 or ±3%	±8.0%
MCV	±5.0%	±6.0%
Plt 0-50	±10.0 or ±10%	±15.0 x 10^3 cells/µL
51-250	±10.0 or ±10%	±30%
251-500	±10.0 or ±10%	±60.0 x 10^3 cells/µL
501-999	±10.0 or ±10%	±12%
LY% 20 - 40	±5.0%	

Table 4.4 CBC Accuracy at 16-35°C

Parameter	Difference (whichever is greater)	95% Confidence
WBC # 0-2.0	±0.4 or ±5%	±0.4 x 10^3 cells/µL
2.1 - 4.0	±0.4 or ±5%	±0.5 x 10^3 cells/µL
≥ 4.1	±0.4 or ±5%	±15%
RBC	±0.4 or ±5%	±12.0%
Hgb	±0.5 or ±5%	±10.0%
MCV	±5.0%	±6.0%
Plt 0-50	±20.0 or ±10%	±25 x 10^3 cells/µL
51-250	±20.0 or ±10%	±35%
251-500	±20.0 or ±10%	±70 x 10^3 cells/µL
501-999	±20.0 or ±10%	±15%
LY% 20 - 40	±5.0%	

Individual CBC parameter results that are flagged by algorithm generated flags or replaced by non-numeric values are excluded from analysis.

Linearity

When tested using a stable sample having no interfering substances, the A^C•T Series instrument values are equal to the expected value within the limits in Table 4-5. To get these same results, subtract background counts from the A^C•T Series instrument values and take multiple readings at each point to eliminate statistical effects of imprecision. Linearity limits apply only to directly measured parameters.

Table 4.5 Linearity Limits

Parameter	Linearity Range	Units	Difference (whichever is greater)
WBC	0 - 99.9	x 10^3 cells/µL	±0.3 or ±5.0%
RBC	0 - 7.0	x 10^6 cells/µL	±0.05 or ±5.0%
Hgb	0 - 25.0	g/dL	±0.2 or ±3.0%
Plt	0 - 999.0	x 10^3 cells/µL	±10.0 or ±10.0%

Background Counts

See Table 4-6 for the maximum acceptable background counts.

Table 4.6 Background Counts

Parameter	Units	Count
WBC	x 10^3 cells/µL	≤0.4
RBC	x 10^6 cells/µL	≤0.04

Table 4.6 Background Counts

Parameter	Units	Count
Hgb	g/dL	≤0.2
Plt	x 10^3 cells/µL	≤7.0

Carryover

The maximum acceptable high-to-low carryover is less than or equal to 2.0%.

Mode to Mode

The mean difference between the whole-blood mode and the predilute mode will be no greater than 5% for the RBC and Hgb parameters when the two modes are compared at identical temperatures using a predilution prepared by the instrument.

4.3 PERFORMANCE CHARACTERISTICS

Imprecision

Imprecision is stated in terms of Coefficient of Variation for the CBC parameters and Standard Deviation for the Lymph % parameter. Imprecision was determined by simple replicate testing (n=31) with normal whole blood, 4C PLUS cell control at three different levels and by difference analysis of paired tests with clinical specimens.

Table 4.7 Imprecision, Whole Blood in K_3EDTA

Parameter	Mean	SD	CV %
WBC	6.78	NA	1.37
RBC	5.12	NA	1.00
HGB	15.32	NA	0.78
MCV	86.35	NA	0.55
PLT	216.37	NA	3.45
LY%	25.41	0.85	NA

Table 4.8 Imprecision, 4C PLUS Normal Cell Control

Parameter	Mean	SD	CV%
WBC	9.85	NA	1.65
RBC	4.14	NA	1.24
HGB	12.88	NA	1.06
MCV	85.09	NA	0.20
PLT	203.31	NA	2.16
LY%	31.72	0.46	NA

Table 4.9 Imprecision, 4C PLUS Abnormal Low Cell Control

Parameter	Mean	SD	CV%
WBC	4.48	NA	2.49
RBC	2.40	NA	1.21
HGB	6.86	NA	1.18
MCV	76.54	NA	0.37
PLT	63.32	NA	4.50
LY%	25.37	1.15	NA

Table 4.10 Imprecision, 4C PLUS Abnormal High Cell Control

Parameter	Mean	SD	CV%
WBC	19.44	NA	0.96
RBC	5.19	NA	1.02
HGB	17.66	NA	0.80
MCV	93.81	NA	0.24
PLT	377.41	NA	2.81
LY%	33.48	0.33	NA

Accuracy

Accuracy for the CBC and Lymph percent parameters was defined as the agreement between the comparator instrument and the A^C•T Series analyzer using clinical specimens with values covering the expected range of performance. Estimates of agreement were made by pair-difference analysis. The magnitude of the Mean Difference or Mean Percent Difference as well as the correlation coefficient express accuracy.

Non-numeric results and results accompanied by R flags or * flags generated by the test or comparator instrument were then excluded from the data used in the accuracy analysis.

Only parameters affected by individual flags were removed from the accuracy analysis. The "N" number for each parameter in the accuracy analysis may therefore vary.

Table 4.11 ACCURACY, COMPARED SAMPLES 20-25° C WHOLE BLOOD MODE

PARAMETER	UNITS	N	POP. MINIMUM	POP. MAXIMUM	MEAN DIFF.	SD	MEAN% DIFF.	Correlation Coefficient
WBC	x 10^3 cells/µL	135	0.40	54.7	0.15	0.41	1.88	0.9992
RBC	x 10^6 cells/µL	150	1.52	6.10	-0.06	0.07	-1.26	0.9981
HGB	g/dL	150	5.30	16.80	0.00	0.17	0.17	0.9983
MCV	fL	150	62.5	119.5	-0.07	1.38	-0.06	NA

PLT	x 10^3 cells/µL	125	93.0	923.0	3.97	17.30	0.13	0.9974
LY	%	129	0.90	50.70	-0.28	14.53	NA	NA

Table 4.12 Accuracy, Compared Samples16-20°C Whole Blood Mode

Parameter	N	Units	Pop. Minimum	Pop. Maximum	Mean Diff.	SD	Mean% Diff.	Correlation Coefficient
WBC	85	x 10^3 cells/µL	3.6	10.0	0.18	0.14	2.96	0.9960
RBC	85	x 10^6 cells/µL	3.55	5.84	-0.08	0.06	-1.80	0.9960
HGB	85	g/dL	10.0	16.1	0.18	0.19	1.40	0.9883
MCV	85	fL	70.4	98.8	-0.12	0.90	-0.10	NA
PLT	85	x 10^3 cells/µL	134	392	-10.72	8.17	-4.74	0.9901
LY	85	%	16.6	46.4	-1.42	1.53	NA	NA

Table 4.13 Accuracy, Compared Samples 25-35° C Whole Blood Mode

Parameter	N	Units	Pop. Minimum	Pop. Maximum	Mean Diff.	SD	Mean% Diff.	Correlation Coefficient
WBC	67	x 10^3 cells/µL	3.6	10.0	0.11	0.30	2.01	0.9749
RBC	67	x 10^6 cells/µL	3.55	5.84	0.06	0.12	1.78	0.9680
HGB	67	g/dL	10.0	16.1	0.12	0.11	0.96	0.9957
MCV	67	fL	70.4	98.8	0.05	0.74	0.08	NA
PLT	67	x 10^3 cells/µL	134	361	4.84	18.83	1.76	0.9520
LY	67	%	16.6	46.4	1.97	2.67	NA	NA

Reference Ranges

A Normal Range Study was conducted to assess the Reference Ranges for the A^C•T Series analyzer. Whole-blood samples were collected from 50 donors (equal numbers of males and females). The selection of donors was consistent with guidelines stated in NCCLS, C28-A.

Table 4.14 Normal Population Study

Parameter	Units	Sex	Mean	95% Conf. Low Limit	95% Conf. High Limit
WBC	$x10^3$ cells/µL	M/F	6.32	3.43	10.94
RBC	$x10^6$ cells/µL	M/F	4.44	3.71	5.56
HGB	g/dL	M/F	13.33	11.76	15.44
HCT	RATIO	M/F	38.00	33.48	43.88
MCV	fL	M/F	86.16	71.07	96.31
MCH	pg	M/F	30.30	24.00	33.86
MCHC	g/dL	M/F	35.11	33.77	36.01
PLT	$x10^3$ cells/µL	M/F	246.05	162.26	370.52
LY	%	M/F	30.34	19.16	44.03

Carryover

Carryover was measured by analyzing three consecutive samples of normal whole blood (H1, H2, H3) followed by three consecutive blank cycles (air) (L1, L2, L3). This sequence was repeated 10 times. Mean Values for each directly measured parameter (WBC, RBC, Hgb, Plt) for each sample type (L1, L2, L3, and H1, H2, H3) were calculated. These Mean Values were then used in the following calculation:

High-to-Low Carryover (H/L%):= ((L1 - L3)/(H3)) x 100

Table 4.15 Imprecision Analysis By Carryover
Whole Blood Mode

Parameter	High To Low Carryover	Unit Of Measure
WBC	1.22	%
RBC	0.00	%
HGB	0.00	%
PLT	0.00	%

Mode to Mode

Mode-to-mode testing included analysis of normal and abnormal whole blood specimens in both the Whole Blood and Predilute modes on the A^C•T Series Analyzer. The Mean Values for WBC, RBC, Hgb, and Plt for each mode were calculated. The individual differences, the average expressed as a mean, and the mean percent difference for each of the four parameters were calculated.

Table 4.16 Whole Blood Mode vs. Predilute Mode

Parameter	N	Whole Blood Mean	Predilute Mean	Mean Diff	Mean % Diff
WBC	74	13.28	13.44	0.16	2.21
RBC	82	3.38	3.41	0.04	1.40
HGB	82	10.19	10.24	0.05	0.72
PLT	60	376.22	383.44	7.22	1.70

4.4 INTERFERING SUBSTANCES

Beckman Coulter recommends you use K_3EDTA as the anticoagulant. You may also use K_2EDTA and Na_2EDTA. Use of other anticoagulants can yield misleading results.

The presence of certain interfering substances, as listed in this section, can also yield misleading results.

WBC

Certain unusual RBC abnormalities that resist lysing, nucleated RBCs, fragmented WBCs, any unlysed particles greater than 35 fL, very large or aggregated platelets as when anticoagulated with oxalate or heparin.[25,26,27,28]

RBC

Very high WBC count, high concentration of very large platelets, agglutinated RBCs and RBCs smaller than 36 fL.[29,30]

Hgb

Very high WBC count, severe lipemia, certain unusual RBC abnormalities that resist lysing, anything that increases the turbidity of the sample such as elevated levels of triglycerides.[31]

MCV

Very high WBC count, high concentration of very large platelets, agglutinated RBCs, RBC fragments that fall below the 36-fL threshold, rigid RBCs.[32,33,34,35]

Plt

Very small red blood cells near the upper threshold, cell fragments, clumped platelets as with oxalate or heparin, platelet fragments or cellular debris near the lower platelet threshold.[36,37,38,39]

Hct

Known factors that interfere with the parameters used for its computation, RBC and MCV.

MCH

Known factors that interfere with the parameters used for its computation, Hgb and RBC.

MCHC

Known factors that interfere with the parameters used for its computation, Hgb, RBC and MCV.

LY

Known factors that affect the WBC count as listed above, high triglycerides that can affect lysing.

5.1 CAUTIONS

Definition

A CAUTION is a notice that an action might damage the instrument.

List of CAUTIONS

System integrity might be compromised and operational failure might occur if:

- You use this equipment in a manner other than specified. Operate the instrument as instructed in the Product Manuals.
- You introduce software that is not authorized by Beckman Coulter into your computer. Only operate your system's computer with software authorized by Beckman Coulter.

Be sure to use only the software card that Beckman Coulter supplies. Observe the copyright statement on the card. If your software card does not work, call your Beckman Coulter Representative for a replacement.

If there is a power failure or brownout, turn the instrument off. When the power returns, turn the instrument back on. It automatically reboots. If you are processing a sample when you turn the instrument off, you lose the sample's results. You must rerun the sample when you turn the instrument back on.

5.2 IMPORTANTS

Definition

An IMPORTANT is a notice that an action might cause misleading results or corruption of data.

List of IMPORTANTS

Before you run or service this instrument, be sure to read all documentation.

When you operate the instrument, be sure that all covers and doors are closed.

When you run a Startup, be sure to get a record of the results. Put the record in your logbook.

In rare instances, a transient or partial aperture blockage may not be detected. Therefore, you are advised to verify flagged results for accuracy and review any result that exceeds your patient reference ranges.

Analyze a whole blood sample within 24 hours of collection.

Allow a prediluted sample to stabilize in the predispensed diluent for at least two minutes.

Analyze a prediluted sample within four hours of preparation.

When you enter the sample identification number, check it on the touch screen display to be sure it is correct.

Mix the sample gently but thoroughly before you cycle it. Invert the sample at least 8 times.

Verify all manually entered data.

Periodically check the reagent expiration date on the reagent container label.

When storing samples:

- Do not refrigerate samples for Platelet and differential counts.
- If you do not need Platelet or differential results, you can store whole-blood specimens drawn in a salt of EDTA at 2 to 8°C.
- Warm samples to room temperature before you cycle them.

When processing samples:

- Be sure there is enough properly mixed sample in the tube for complete aspiration.
- Hold the tube up to the probe, with the probe well into the sample. When the system aspirates the sample, the probe moves up and into the instrument.
- Remove the tube when you hear the audible alarm.

Abnormal low results for WBC, RBC, Hgb and Plt may indicate incomplete aspiration. If abnormal low results occur, cycle the sample again.

Ignore H or L flags next to 4C PLUS cell control results. These flags are used to identify patient sample results that recover outside of your patient limits.

If any parameter's result is over linearity range (**+**) or over operating range (**+++++**), run a blank sample:

Wait for the cycle to finish before you run another sample.

If a printout is not clear, do not use it. Replace the printer ribbon or have the printer fixed, then rerun the sample. Do not write results on the printout.

If two or more samples have the same ID#, use the date and time on the printout to distinguish between them.

5.3 WARNINGS

Definition

Anything that can cause injury to the operator is considered a hazard. A hazardous condition is noted in text as a WARNING.

Biological Hazards

Beckman Coulter, Inc. urges its customers to comply with all national health and safety standards, such as the use of barrier protection. This may include, but is not limited to, protective eye wear, gloves, and suitable laboratory attire when operating or maintaining this or any other automated laboratory analyzer.

To avoid being exposed to biohazardous material, adhere to standard laboratory safety procedures, including:

- wearing protective gloves
- wearing protective goggles or using a biohazard shield

- wearing a lab coat.

Waste can include biohazardous material. Dispose of it according to acceptable laboratory practices.

Do not overfill the waste container. When the waste container full message appears, replace the waste container with an empty one.

Be sure the waste container is in a safe place and is properly connected.

Take all appropriate precautions when you are processing samples and handling the sample tube.

When you operate the instrument, be sure all covers and doors are closed.

Moving Parts

When you operate the instrument, be sure all covers and doors are closed.

If the probe is loose or bent, do not run the instrument. Call your Coulter Representative.

The peristaltic pumps rotate at various intervals during a normal run. Do not put your hands in the area.

This Appendix contains these Log Sheets. Make photocopies of them as needed.

Action Log
Maintenance Log
Reagent Log
Calibration Worksheet

Table 1.1 ACTION LOG

Date	By	Activity

Serial No. _____ Lab._____

COULTER® A^{C}•T Series

Table 1.2 MAINTENANCE LOG

Date	By	Activity

Serial No. _____ Lab._____

COULTER® A^{C}•T Series

Table 1.3 REAGENT LOG

Date Opened	Lot Number	Expiration Date	Who Changed it

Serial No. _____ Lab._____

COULTER® A^{C}•T Series

CALIBRATION WORKSHEET

Sample Number	WBC	RBC	Hgb	MCV	Plt
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
TOTAL					
MEAN (A)					
ASSIGNED VALUE (B)					
ABSOLUTE DIFFERENCE (C)					
CALIBRATION REQUIRED					
CURRENT CALIBRATION FACTOR (D)					
NEW CALIBRATION FACTOR (E)					

A = sample numbers 2 through 11
C = B - A
E = (B / A) x D

COULTER® A^{C}•T Series

REFERENCES

1. Coulter WH. High speed automatic blood cell counter and cell size analyzer. Paper presented at National Electronics Conference, Chicago, IL, 1956; October 3.
2. Brecher GM, Schneiderman M and Williams GZ. Evaluation of electronic red blood cell counter. Am J Clin Path, 1956; 26:1439-1449.
3. Brittin GM, Brecher G and Johnson CA. Evaluation of the COULTER COUNTER® Model S. Am J Clin Path, 1969; 52:780-783
4. Gottmann NAW. Multiple hematologic analyses by means of a COULTER COUNTER Model S. Paper presented at International Symposium of Standardization of Hematological Methods, Fondazione, Carlo Erba, Milan, Italy, November 9 and 10, 1970. Symposium proceedings published in Haematologica Latina, 1969.
5. Hamilton PJ and Davidson RL. The interrelationships and stability of Coulter S-determined blood indices. J Clin Path, 1973; 16:700-705.
6. Bessman JD and Johnson RK. Erythrocyte volume distribution in normal and abnormal subjects. Blood, 1975; 46:369-379.
7. Price-Jones. The diameter of red cells in pernicious anaemia and in anaemia following haemorrhage. J Path Bact, 1922; 25:487-504.
8. England JM, Walford DM and Waters DAW. Reassessment of the reliability of the haematocrit. Brit J Haemat, 1972; 23:247-256.
9. Bull BS, Schneiderman MA and Brecher G. Platelet counts with the COULTER COUNTER®. Am J Clin Path, 1965; 44(6):678-688.
10. Mundschenk DD, et al. An improved technique for the electronic measurement of platelet size and shape. J Clin Lab Med, 1976; 88(2):301-315.
11. Schulz J and Thom. Electrical sizing and counting of platelets in whole blood. Med Biol Engr, 1973; 73:447-454.
12. Von Behrens. Mediterranean macrothrombocytopenia. Blood, 1975; 46(2):199-207.
13. Paulus JM. Platelet size in man. Blood, 1975; 46(3):321-336.
14. International Committee for Standardization in Haematology. Recommendations for reference method for haemoglobinometry in human blood (ICSH Standard EP6/2:1977) and specifications for international haemiglobincyanide reference preparation (ICSH Standard EP6/3: 1977) J Clin Path, 1978; 31(2):139-143.
15. Gauthier et al. Human leukocytes: their size distribution and mean corpuscular volume. Can Med Assn J, 1967; 97:793-796.
16. Hughes-Jones NC et al. Differential leukocyte counts by volume distribution analysis. Brit J Hem, 1974; 28(1):148.
17. England JM et al. A semi-automatic instrument for estimating the differential leukocyte count. Biomed Engr, 1975; 10(8):303-304.
18. Wycherley PA and O'Shea MJ. Abridged differential leukocyte counts provided by a COULTER® Channelyzer in a routine haematology laboratory. J Clin Path, 1978; 31(3):271-274.

19. Oberjat TE, Zucker RM and Cassen B. Rapid and reliable differential counts on dilute leukocyte suspensions. J Lab Clin Med, 1978; 76(3):518-522.

20. Cox C et al. Evalution of COULTER®, three part differential system. Am J Clin Path, 1984; 82(3):372-373.

21. Eckhoff RF. An experimental indication of the volume proportional response of the Coulter Counter for irregularly shaped particles. J Sci Inst, 1967; 44:648-649.

22. Grover NB, Naaman J, Ben-asson S and Dojanski F. Electrical sizing of particles in suspension III. Rigid spheroids and red blood cells. Biophys J, 1972; 12:1099-1116.

23. Waterman CS, Atkinson EE, Wilkins B, Fischer CL and Kimsey SL. Improved measurement of erythrocyte volume distribution by aperture-counter signal analysis. Clin Chem, 1975; 21:1201-1211.

24. Kachel V and Ruhenstroth-Bauer G. Methodik and Ergebissne Optiseher Formfatorunter-suchungen bei der Zellvolumenmessung nach Coulter. Micros Acta, 1976; 75:419-423.

25. Luke RG, Koepke JA and Siegel RR. The effect of immunosuppressive drugs and uremia on automated leukocyte counts. Am J Clin Path 11971; 56:503-507.

26. Koepke JA. Drug interference with leukocyte counting (spurious leukopenia). Drug Therapy, 1974; 79.

27. Dale NL and Schumacher HR. Platelet satellitism -- new spurious results with automated instruments. Lab Med, 1982; 13:300-304.

28. Kjeldsberg CR and Hershgold EJ. Spurious thrombocytopenia. JAMA, 1974; 227:628-630.

29. Brittin GM, Brecher G, Johnson CA and Stuart J: 1969. Spurious macrocytosis of antibody-coated red cells. Am J Clin Path 52:237-241.

30. Hattersley PG, Gerard PW, Caggiano V and Hash DR. Erroneous values on the COULTER COUNTER® Model S due to high titer cold autoagglutinins. Am J Clin Path, 1971; 55:442-446.

31. Nosanchuk JS, Roark MF and Wanser C. Anemia masked by triglyceridemia. Am J Clin Path, 1974; 62:838-839.

32. Brittin GM, Brecher G, Johnson CA and Stuart J: 1969. Spurious macrocytosis of antibody-coated red cells. Am J Clin Path 52:237-241.

33. Nosanchuk JS, Roark MF and Wanser C. Anemia masked by triglyceridemia. Am J Clin Path, 1974; 62:838-839.

34. Waterman CS, Atkinson EE, Wilkins B, Fischer CL and Kimsey SL. Improved measurement of erythrocyte volume distribution by aperture-counter signal analysis. Clin Chem, 1975; 21:1201-1211.

35. Fales W. Water distribution in blood during sickling of erythrocytes. Blood, 1978; 51:703-709.

36. Kjeldsberg CR and Hershgold EJ. Spurious thrombocytopenia. JAMA, 1974; 227:628-630.

37. Dale NL and Schumacher HR. Platelet satellitism -- new spurious results with automated instruments. Lab Med, 1982; 13:300-304.

38. Waterman CS, Atkinson EE, Wilkins B, Fischer CL and Kimsey SL. Improved measurement of erythrocyte volume distribution by aperture-counter signal analysis. Clin Chem, 1975; 21:1201-1211.

39. Fales W. Water distribution in blood during sickling of erythrocytes. Blood, 1978; 51:703-709.

Accuracy	Ability of the instrument to agree with a predetermined reference value at any point within the operating range.
Assay Values	Values of all parameters in a control established by extensive assay of that control.
Assigned Values	Values of all parameters in a calibrator established by extensive testing of that calibrator.
Background Count	Measure of the amount of electrical or particle interference.
Baud	A rate defining how many data bits per second are transferred during communications between two pieces of equipment.
Blank Cycle	Runs diluent through the system to clean it out.
Calibration	A procedure to standardize the instrument by determining its deviation from calibration references and applying any necessary correction factors.
Calibration Factors	These are correction factors that the system uses to fine-tune instrument accuracy.
Carryover	The amount, in percent, of blood cells or Hgb remaining in diluent following the cycling of a blood sample.
Cell Control	A preparation made of human blood with stabilized cells and surrogate material. It is used for daily instrument quality control.
Codes	On printouts, symbols such as +++++, -----, ..., +, * that appear in place of sample results. See Heading 3.2, What Flags Mean, of the Special Procedures and Troubleshooting manual for additional information.
Coefficient of Variation	An expression, in percent, of data (SD) spread as related to the mean. %CV = (SD / mean) 100
Coincidence	More than one cell within aperture sensing boundaries at the same time. The system senses these as one large cell rather than as two distinct cells, so it generates one large pulse.
CV	(see Coefficient of Variation)
Data Bit	Computer code used to transfer each character of information.
Defaults	Original settings in the instrument. You can change these to tailor operation to your situation.
Expiration Date	The last day when you can use that lot number of reagent, control or calibrator.
Field	Area on a screen for entering data.
Flags	On printouts, letters (H, L, *, +) that appear next to parameter results to indicate specific conditions. See What Flags Mean, Heading 3.2 in the **Special Procedures and Troubleshooting** manual for additional information.
Hemoglobinometry	Measurement of hemoglobin in the blood. In Beckman Coulter instruments, this is done by comparing the amount of light that passes through a diluted lysed sample in which the released Hgb has been chemically converted, with the amount of light that passes through a blank.
IQAP (Interlaboratory Quality Assurance Program)	Beckman Coulter, Inc. provides this program which statistically compares your 4C PLUS cell control data to a group of other laboratories' control recovery data.
Linearity	The ability of an instrument to recover expected results (reference values or calculated values) for such parameters as WBC, RBC, Hgb and Plt at varying levels of concentration of these parameters within specified limits.
Lot Number	A manufacturer's code that identifies when the reagent was manufactured.
Mean	Arithmetic average of a group of data.

Outlier	Control result that falls outside the expected range.
Parameters	Components of blood that the instrument measures and reports.
Parity	Method of detecting errors in data handling. The computer generates a parity bit such that the sum of the data bits and the parity bit are odd or even for each data word.
Precision	Ability of the instrument to reproduce similar results when a sample is run repeatedly. Precision of the instrument is a %CV, or an SD for diff parameters, based on at least 31 replicate determinations of the same sample. Precision shows the closeness of test results when repeated analyses of the same material are performed. Also called reproducibility.
QC (Quality Control)	A comprehensive set of procedures your laboratory sets up to ensure that the instrument is working accurately and precisely.
Reagent Management Card	**A program card that manages your reagent usage.**
Reproducibility	This procedure checks that the system gives similar results (within established limits) every time it measures the same sample. Also called precision.
SD (Standard Deviation)	A measure of difference from the mean.
Shift	Consecutive values that abruptly move from one side of the mean to the other then maintain a constant level.
Software Card	**A program card that contains instructions to run the instrument.**
Standard Deviation (SD)	A measure of difference from the mean.
Stop Bit	A computer code that indicates the end of a character.
Sweep Flow	A steady stream of diluent that flows behind the RBC aperture during sensing periods to keep RBCs from swirling back into the sensing zone.
Trend	Values that continue to increase or decrease gradually over a period of time.
Verification	Procedure to analyze cell controls or whole blood with known values to determine if your control results are within expected range.
Voting	In Beckamn Coulter hematology instruments, the system compares the three counts for RBC, WBC, Plt. Unless at least two counts agree, the system does not accept the count. It displays a code (-----) to indicate a voteout.

Numerics

4C PLUS cell control, 1-3

A

Ac•T 10‡, 1-1
Ac•T 8, 1-1
AC•T Rinse, 1-4
AC•T Tainer, 4-1
Ac•T Tron‡ cell control, 1-3
accuracy, 4-4
action log, A-3
ambient temperature and humidity, 2-1
analyzer, 1-1, 1-2
anticoagulant, 4-2
aperture, 3-1
Aperture Alert, 3-4
aperture size, 4-2

B

background counts, 4-6
biological hazards, 5-2

C

calibration worksheet, A-9
calibrator, 1-3, 4-2
carryover, 4-7
cautions, 5-1
cell controls, 1-3
    4C PLUS cell control, 1-3
    Ac•T Tron‡ cell control, 1-3
    controls, 4-2
coincidence correction, 3-3
computed parameters, 3-4
computer software, 1-4
conventions, x
COULTER COUNTER, 1-2
Coulter method, 1-2, 3-1
Coulter Principle, 1-2
counting, 3-2
counting and sizing cells, 3-2
    aperture alert, 3-4
    coincidence correction, 3-3
    computed parameters, 3-4
    Plt distribution, 3-3
    RBC distribution, 3-3
    red and white cells, 3-2
    sweep flow, 3-3
    voting, 3-3
    WBC distribution, 3-3

D

delivery inspection, 2-1
diagnostic functions, xiv
diluent, 1-4
diluter functions, xiii
dimensions, 4-1

E

electrical input, 2-1
erythrocyte, 1-1

H

hemoglobin, 1-3
    measurement, 3-5
hemoglobin (Hgb)
    measurement, 3-5
hemoglobin method, 1-3
humidity, 2-1, 4-1

I

importants, 5-1, 5-2
imprecision, 4-2
installation, 2-1
    ambient temperature and humidity, 2-1
    delivery inspection, 2-1
    electrical input, 2-1
    printer, 2-1
    reagent connections, 2-1
    space and accessibility, 2-1
instrument specifications, 4-1
    anticoagulant, 4-2
    aperture size, 4-2
    calibrator, 4-2
    dimensions, 4-1
    humidity, 4-1
    output, 4-2
    power, 4-1
    recommended reagents, 4-1
    sample indentification, 4-2
    sample volume aspirated, 4-2
    storage, 4-2
    temperature, ambient operating, 4-1
    throughput, 4-2

weight, 4-1
intended use, 1-1
interfering substances, 4-14

L

leukocyte, 1-1
leukocyte volume, 1-3
linearity, 4-6
log sheets, A-1
lytic reagent, 1-4

M

main screen, xi
maintenance log, A-5
material safety data sheets, 1-4
mode to mode, 4-7
moving parts, 5-3

N

normal sample flow, 3-1

O

operating range, 4-3
output, 4-2

P

parameters
computed, 3-4
definitions, 1-1
derivation, 3-5
performance specifications, 4-2
accuracy, 4-4
background counts, 4-6
carryover, 4-7
imprecision, 4-2
linearity, 4-6
mode to mode, 4-7
operating range, 4-3
platelet (Plt)
count and size distribution, 3-3
Plt distribution, 3-3
power, 4-1
printer, 2-1

R

RBC distribution, 3-3
reagent
connections, 2-1
description, 1-3
effect of, 3-1
I, 1-4
II, 1-4
reagent connections, 2-1
reagent log, A-7
reagents, 1-3
recommended reagents, 4-1
red blood cell (RBC)
count and size distribution, 3-3
counting, 3-2

S

sample
identification, 4-2
volume, 4-2
sample ID, xv
sample identification, 4-2
sample results, xv
sample volume aspirated, 4-2
samples
output, 4-2
sample identification, 4-2
storage, 4-2
throughput, 4-2
S-CAL kit, 1-3
screen
diagnostic functions, xiv
diluter functions, xiii
main screen, xi
sample ID, xv
sample results, xv
setup, xii
setup, xii
shutdown diluent, 1-4
sizing, 3-2
space and accessibility, 2-1
specifications
instrument, 4-1
performance, 4-2
storage, 4-2
sweep flow, 3-3
symbols, x

T

temperature, 2-1, 4-1
temperature, ambient operating, 4-1
thrombocyte, 1-2
throughput, 4-2

U

use and function, 1-1

V

voting, 3-3

W

warnings, 5-2
  biological hazards, 5-2
  moving parts, 5-3
WBC distribution, 3-3
white blood cell (WBC)
  count and size distribution, 3-3
  counting, 3-2

BECKMAN COULTER, INC. CUSTOMER END USER LICENSE AGREEMENT

This Product contains software that is owned by Beckman Coulter, Inc. or its suppliers and is protected by United States and international copyright laws and international trade provisions. You must treat the software contained in this Product like any other copyrighted material. This license and your right to use the Product terminate automatically if you violate any part of this agreement.

This is a license agreement and not an agreement for sale. Beckman Coulter hereby licenses this Software to you under the following terms and conditions:

You May:

1. Use this software in the computer supplied to you by Beckman Coulter;
2. Maintain one copy of this software for backup purposes (the backup copy shall be supplied by Beckman Coulter);
3. After written notification to Beckman Coulter, transfer the entire Product to another person or entity, provided you retain no copies of the Product software and the transferee agrees to the terms of this license agreement.

You May Not:

1. Use, copy or transfer copies of this Software except as provided in this license agreement;
2. Alter, merge, modify or adapt this Software in any way including disassembling or decompiling;
3. Loan, rent, lease, or sublicense this Software or any copy.

Limited Warranty

Beckman Coulter warrants that the software will substantially conform to the published specifications for the Product in which it is contained, provided that it is used on the computer hardware and in the operating system environment for which it was designed. Should the media on which your software arrives prove defective, Beckman Coulter will replace said media free of charge within 90 days of delivery of the Product. This is your sole remedy for any breech of warranty for this software.

Except as specifically noted above, Beckman Coulter makes no warranty or representation, either expressed or implied, with respect to this software or its documentation including quality, performance, merchantability, or fitness for a particular purpose.

No Liability for Consequential Damages

In no event shall Beckman Coulter or its suppliers be liable for any damages whatsoever (including, without limitation, damages for loss of profits, business interruption, loss of information, or other pecuniary loss) arising out of the use of or inability to use the Beckman Coulter Product software. Because some states do not allow the exclusion or limitation of liability for consequential damages, the above limitation might not apply to you.

General

This agreement constitutes the entire agreement between you and Beckman Coulter and supersedes any prior agreement concerning this Product software. It shall not be modified except by written agreement dated subsequent to the date of this agreement signed by an authorized Beckman Coulter representative. Beckman Coulter is not bound by any provision of any purchase order, receipt, acceptance, confirmation, correspondence, or otherwise, unless Beckman Coulter specifically agrees to the provision in writing. This agreement is governed by the laws of the State of Florida.

BECKMAN COULTER™

All other trademarks, service marks, products, or services are trademarks or registered trademarks of their respective holders.

COULTER® AC•T SERIES DOCUMENTATION

- **Reference**
  PN 4237288
  Use and Function • Installation • Operation Principles • Specifications/ Characteristics • Precautions and Hazards • Appendix • References • Glossary • Index

- **Operator's Guide**
  PN 4237287
  Using this Document • Screen Symbols • Warnings/Instructions • Run Samples - Whole Blood Mode • Run Samples - Predilute Mode • Startup • Run Controls • Shutdown • Review Results

- **Getting Started**
  PN 4237289
  Installing the AC•T • Learning about the AC•T • Using the Instrument • Index

- **Special Procedures and Troubleshooting**
  PN 4237314
  Preventive Maintenance Procedures • Replace/Adjust Prodedures • Index

- **Host Transmission Specification**
  PN 4237283
  Introduction • High-Level Record Field Definitions • Low-Level Protocol Description • Appendices

Come visit us at www.beckmancoulter.com

Copyright © Beckman Coulter, Inc. 2003
All Rights Reserved
Printed on Recycled Paper

BECKMAN COULTER™